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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,180	08/11/2006	Nicola La Monica	ITR0073YP	3924

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EXAMINER	
SGAGIAS, MAGDALENE K	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,180	LA MONICA ET AL.	
	Examiner	Art Unit	
	Magdalene K. Sgagias	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7,8,10-16,20-24,27-30,32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-2, 4-5, 7-8, 10-16, 20-24, 27-30, 32, 34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2, 4-5, 7-8, 10-16, 20-24, 27-30, 32, 34 are pending. Claims 3, 6, 9, 17-19, 25-26, 31, 35 are canceled.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 4-5, 7-8, 10-13 drawn to a nucleic acid molecule comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.

Group II, claim(s) 14-16 and 20, drawn to a vector comprising the nucleic acid molecule of claim 13.

Group III, claim(s) 21, drawn to a process for expressing a CEA fusion protein in a recombinant host cell, comprising (a) introducing a vector comprising the nucleic acid molecule of claim 1 into a suitable host cell; and, (b) culturing the host cell under conditions which allow expression of said human CEA fusion protein.

Group IV, claim(s) 22-23, drawn to a purified CEA fusion protein encoded by the nucleic acid molecule of claim 1.

Group V, claim(s) 24, 27-28, drawn to a method of preventing or treating cancer comprising administering to a mammal a vaccine vector comprising the nucleic acid molecule of claim 1.

Group VI, claim(s) 29-30, drawn to an adenovirus vaccine vector comprising an adenoviral genome with a deletion in the E1 region, and an insert in the E1 region, wherein the insert comprises an expression cassette comprising: (a) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.; and (b) a promoter operably linked to the polynucleotide.

Group VII, claim(s) 32, drawn to a vaccine plasmid comprising a plasmid portion and an expression cassette portion, the expression cassette portion comprising: (a) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FclgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and, (b) a promoter operably linked to the olynucleotide.

Group VIII, claim(s) 33-34, drawn to a method of treating a mammal suffering from or predisposed to a CEA-associated cancer comprising: (a) introducing into the mammal a first vector comprising: (i) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FclgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and, (ii) a promoter operably linked to the polynucleotide; (b) allowing a predetermined amount of time to pass; and (c) introducing into the mammal a second vector comprising: (i) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FclgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and (ii) a promoter operably linked to the polynucleotide.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group II does not require the fusion protein is capable of producing an immune response in a mammal as of Group I. An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See 37 C.F.R 1.475 (a). If multiple products, processes of manufacture, or uses are

claimed, the first invention of the category first mentioned in the claims of the application and first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See 37 C.F.R 1.475 (d) and 37 C.F.R 1.476 (c). Accordingly, Groups I-VIII are not linked by a special technical feature.

Inventions I-II, IV, VI-VII are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the vector of group II can be used for in vitro studies of the CEA nucleic acid. The CEA nucleic acid of group I can be used for drug screening in a mammal. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III, V and VII are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions of the groups III, V and VII are distinct each from the other because they are drawn to methods that have distinct steps, require separate compositions for practice and produce different product or results. For example, the steps of (a) introducing a vector comprising the nucleic acid molecule of claim 1 into a suitable host cell; and, (b) culturing the host cell under conditions which allow expression of said human CEA fusion protein cannot be used in preventing or treating cancer comprising administering to a mammal a vaccine vector comprising the nucleic acid molecule of claim 1.

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I-II, IV, VI-VII and III, V, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the compositions of the group's I-II, IV, VI-VII are patentably distinct each from the methods of the group's III, V, VIII because these methods cannot be used to produce the compositions. Alternatively, the composition may not be used in the methods or will be used in more than one method. Therefore, the inventions of the group's I-VIII are patentably distinct each from the other and will require separate and non-coextensive searches in the patent and non-patent literature. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

A. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

B. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

C. ***Species election***

This application contains claims directed to the following patentably distinct species:

Claims 1, 27-29, 32, 33 and its depended claims contain the following patentably distinct species: DOM, FclgG, CT, LTA, and LTB.

Claim 2 and its depended claims contain the following patentably distinct species: human CEA protein or variant thereof or a rhesus monkey CEA protein or variant thereof.

Claim 10 and its depended claims contain the following patentably distinct species: SEQ ID NOs: 7, 9, 11, 12, 14, 21, 25, 49, 50, and 52.

Claims 16, 30 and its depended claims contain the following patentably distinct species: Ad5, or Ad6, or Ad24.

Claim 23 and its depended claims contain the following patentably distinct species: SEQ ID NOS:8, 10, 13, 15, 45, 46, 51, and 53.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571)272-3305. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Anne-Marie Falk/
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